CONFIDENTIAL K021021

JUN 6 2002

510(K) SUMMARY

Submitted by:
Siemens Medical Solutions USA, Inc.
186 Wood Avenue South
Iselin, NJ 08830

March 22, 2002

This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR § 807.92.

1. **Contact Person**

Ms. Sandra Robinson
Phone: (732) 321-3243 Fax: (732) 321-4841

2. **Device Name and Classification**

Trade Name:	Modular Angiography System AXIOM Artis with Flat Panel Detector
Classification Name:	Angiographic X-ray System
Classification Panel:	Radiology
CFR Section:	21 CFR § 892.1600
Device Class:	Class II
Device Code:	90IZI

3. **Intended Use**

AXIOM Artis is a dedicated angiography system developed for single and biplane diagnostic imaging and interventional procedures.

AXIOM Artis can support the acquisition of position triggered imaging for spatial data synthesis. When equipped with the AXIOM OR table from the Koordinat Table family, the Modular Angiography System is suitable for angiographic procedures in operating rooms.

4. **Substantial Equivalence**

AXIOM Artis with Dynamic Flat Panel Detector is substantially equivalent to the current, commercially available Siemens AXIOM Artis and the GE Angiographic systems, the INNOVA 2000. The Flat Panel detector Trixell Pixium 4800 is a joint venture development between Thales, Philips and Siemens. It may be used with the Siemens AXIOM Artis and the Philips Integris Allura.
The AXIOM Artis was described in premarket notification K010721 and received FDA clearance on March 30, 2001. The Philips Integris Allura Flat Detector system with the Trixell Pixium 4800 was described in premarket notification (510(k) number not yet published) and received FDA clearance on March 15, 2002. INNOVA 2000 was described in premarket notification K993037 and received FDA clearance on February 14, 2000.

Information that substantiates this claim of equivalence is provided throughout this 510(k) submission and specific equivalence information is provided in Attachment 5.

5. **Device Description**

The AXIOM Artis Modular Angiography System with Dynamic Flat Panel detector is designed as a set of components that may be combined into different configurations to provide specialized angiography systems. It is basically equal to the AXIOM Artis Modular Angiography System family with all its components. A new Flat Panel detector has been adapted to the system. The detector is comprised of a large area amorphous silicon layer. Flat screen monitors for diagnostic review are optional available.

6. **Summary of Technological Characteristics of the Principal Device as Compared with the Predicate Device**

Many of the components used in AXIOM Artis with Dynamic Flat Panel detector are either commercially available with current Siemens systems or include minor modifications to existing components.

7. **General Safety and Effectiveness Concerns**

Instructions for use are included within the device labeling and the information provided will enable the trained healthcare professional to operate the device in a safe and efficacious manner. Furthermore the operators are health care professionals familiar with and responsible for the X-ray examinations to be performed. To minimize electrical, mechanical and radiation hazards, Siemens adheres to recognized and established industry practice, and all equipment is subject to final performance testing.

8. **Substantial Equivalence**

In the opinion of Siemens Medical Solutions USA, Inc., the hardware and software documentation and the substantial equivalence comparison matrix proves that the AXIOM Artis with Flat Panel Detector is substantially equivalent to the Siemens Medical Solutions USA, Inc. predicate Angiography systems - the AXIOM Artis family of Modular Angiography systems, the Philips Integris Allura Flat Detector system and the GE's Medical System INNOVA 2000.

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

Ms. Kathleen Rutherford
Manager, Regulatory Submissions
Siemens Medical Solutions USA, Inc.
186 Wood Avenue South
ISELIN NJ 08830

AUG 20 2013

Re: K021021
Trade/Device Name: Modular Angiography System AXIOM Artis with Flat Panel Detector
Regulation Number: 21 CFR 892.1650
Regulation Name: Image-intensified fluoroscopic x-ray system
Regulatory Class: II
Product Code: JAA and IZI
Dated: March 22, 2002
Received: March 29, 2002

Dear Ms. Rutherford:

This letter corrects our substantially equivalent letter of June 6, 2002.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely Yours,

Janine M. Morris
Acting Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

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Attachment 1

Indications For Use

510(k) Number (if known):_____
Device Name: Modular Angiography System AXIOM Artis with Flat Panel Detector

Indications for Use:

AXIOM Artis is a family of dedicated angiography systems developed for single and biplane diagnostic imaging and interventional procedures.

Procedures that can be performed with the AXIOM Artis family include cardiac angiography, neuro-angiography, general angiography, operating room angiography, multipurpose angiography and radiographic/fluoroscopic procedures e.g. Gastro-intestinal imaging, Skeletal imaging etc.
AXIOM Artis can also support the acquisition of position triggered imaging for spatial data synthesis.

The intended use and indications for use of the *Modular Angiography System AXIOM Artis with Flat Panel Detector* as described in its labeling have not changed from its predicate device AXIOM Artis *with the image intensifier.*

(Please do not write below this line - continue on another page if needed)

Concurrence of the CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use_____
(Per 21 CFR 801.109)

David A. Ayres

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K021021